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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,618	07/22/2003	Tae Kook Kim	2001180-0078	6583

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,618	KIM, TAE KOOK	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 22 July 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S-a 3

DETAILED ACTION

This is the First Office Action on the Merits of the application filed 22 July 2003, which is a divisional of application 09/999,054 filed 25 October 2001, which claims benefit of provisional application 60/243,689 filed 27 October 2000. Claims 1-26, as originally filed, are pending.

Priority

The first line of the specification makes reference to the priority applications but fails to include the current status of the '504 application, which is now US Patent No. 6,596,506. Applicant is reminded that the status of nonprovisional parent applications (whether patented or abandoned) should also be included in the reference. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. Applicant is urged to amend the reference to the priority applications to include the final status of the '504 application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying a compound that affects stability of a protein of

interest comprising the process steps set forth in the claims and further comprising steps wherein levels of the fusion protein and control reporter protein are determined in the absence of contacting a test compound with cells from the cell line and comparing levels of the fusion protein and control protein determined in the presence of the test compound with levels of fusion protein and control protein determined in the absence of the test compound, does not reasonably provide enablement for a method wherein levels of fusion protein and control reporter protein in the absence of test agent are not determined and compared with levels in the presence of the test compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The claims are directed to a method of identifying compounds that affect the stability of a protein of interest. However, the process steps set forth in the claim require only that a cell line transfected with a construct expressing a reporter protein fused to a protein of interest and also expressing a control reporter protein are contacted with a test compound and a DNA damaging agent. The claim then recites that levels of the fusion protein and the control reporter protein are compared. If one were to practice the method as claimed, the outcome would not identify a compound that affects the stability of a protein because the information obtained would be limited to a ratio of the level of fusion protein relative to control protein in the presence of the test agent. The skilled artisan would not be able to determine the effect of the test compound on

the stability of the protein of interest because the method does not provide any information regarding the level of the fusion protein and control reporter protein in the absence of test agent.

Results obtained in the working examples of the claimed invention (Example 2) are presented as fold induction compared to untreated cells (see especially Figure 5) and there is no disclosure of a method of identifying a compound that affects stability of a protein of interest wherein information related to stability of the protein in the absence of the test agent is irrelevant. In fact, information regarding the state of a system prior to test manipulation is always critical to any method that seeks to determine a change effected by said test manipulation.

For these reasons, the skilled artisan would not be able to identify compounds that affect stability of a protein of interest according to the process steps set forth. Therefore, the claims are properly rejected under 35 USC §112, first paragraph, as lacking essential process steps.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are steps wherein levels of the fusion protein and control reporter protein are determined in the absence of contacting a test compound with cells from the cell line and comparing levels of the fusion protein and control protein determined in the presence of the test compound with levels of fusion protein and control protein determined in the absence of the test compound. As described above, practicing the process steps set forth in the claims would not identify a compound that affects stability of a protein of interest because the method does not

establish the properties of the test system in the absence of the test compound. Instead, the method claimed would merely establish the level of fusion protein expression relative to control reporter protein expression in the presence of test agent, which is not a measure of the effect of the compound on protein stability in the absence of information regarding expression in the absence of the test compound.

Claims 1-26 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 25 and 26 are indefinite in reciting "contacting cells with a DNA damaging agent". As there is no definite or indefinite article modifying "cells", it is unclear whether the cells referred to are related to the cells of the cell line in steps 1 and 2 of the claim or some other cells. In addition, there are two cells that precede the DNA damaging agent contacting step (*i.e.*, the cells of the cell line not contacted with a test compound of the first step and the cells contacted with a test compound of the second step). For these reasons, the antecedent basis of the cells contacted with a DNA damaging agent in the third step is unclear.

Claims 1, 2 and 24 are indefinite in reciting "p53 [p52]-fused to a reporter protein and a control reporter protein". The limitation might be read as requiring that p53 is fused to both a reporter protein and a control reporter protein, or that the construct expresses p53 fused to a reporter protein and separately expresses a control reporter protein that is not fused to p53. As the limitation can be interpreted in different ways, which encompass constructs having significantly different scope, the metes and bounds of the claim as a whole are unclear. It is

noted that the inclusion of a comma in the phrase recited in claim 25 (*i.e.*, "expressing a first reporter protein fused to the protein of interest, and a second control reporter protein") clarifies the scope of the claim by indicating that the claim does not require that the control reporter protein be fused to the protein of interest. Similar use of a comma in claims 1 and 24 would overcome this rejection.

Claim 3 is indefinite in reciting, "the cell line is derived from a cell line known to contain active p53 turnover pathways" and claim 4 is indefinite in reciting, "the cell line is derived from a cell line that has a relatively low steady state level of p53 protein and shows a significant accumulation of p53 protein following treatment with a DNA damaging agent" (emphasis added). Without a clear statement of the process by which the starting material is derivatized it is not possible to know the metes and bounds of such a limitation because any given starting material can have many divergent derivatives depending on the process of derivatization. For example, it is unclear whether the cell line of the claim (*i.e.*, the derivative) must maintain those properties of the starting material recited in the claim (*e.g.*, an active p53 turnover pathway) or whether a cell in which those properties are lost in the process of derivatization would also read on the claim.

Claim 4 is also indefinite in reciting that the cell line is "known to contain" an active p53 turnover pathway. It is unclear whether the claim seeks to require prior knowledge of the property as a limitation of the product. Applicant is reminded that requiring knowledge of a property that might be inherent to a product is inconsistent with patent law. For anticipation or obviousness, there is no requirement that a person of ordinary skill in the art would have recognized an inherent disclosure at the time of invention, but only that the subject matter is in

fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). See also MPEP 2112.

Claims 12-15 are indefinite in reciting that the various proteins are "detectable by" the various methods. It is unclear whether it is Applicant's intention is that the claimed method comprise a step wherein the proteins are detected by the process or reagent recited or whether the claims are merely reciting properties that are inherent to the proteins. If the latter is the case, then the claims do not further limit the base claim because all proteins are detectable by the agents and processes recited in the claims.

Claim 24 is indefinite in reciting "p52-fused to a reporter protein". There is no antecedent basis for "p52". This is presumed to be a typographical error.

Claims 3-23 are also indefinite insofar as they depend from claim 1.

Claim Objections

Claim 16 is objected to because of the following informalities: The phrase "the control reporter protein are translated" is grammatically incorrect.

Appropriate correction is required.

Double Patenting

Applicant is advised that should claim 25 be found allowable, claim 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.
Examiner
Art Unit 1636

DANIEL M. SULLIVAN
PATENT EXAMINER